Psychoeducational Course for Suicide Prevention - a Randomized Controlled Trial

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1. **Project title:**
   Psychoeducational course to handle risk of suicide – a randomized controlled trial

2. **Introduction**

This project evaluates a group based psychoeducational training course by comparing it with one individual session developing a safety plan in a

regional, randomized controlled study. The main aim of the course is to increase the patients' and their relatives' awareness of symptoms and behaviour changes that may indicate an acute episode of increased risk of suicide and how to prevent, how to act, and how to seek help.

Prevalence: In Norway, suicide is considered the third most important cause of years of life lost in men (1). The suicide rate in Norway has been relatively stable since 1995 with 500-600 incidents per year (2). In other western countries, the prevalence has been rising despite large public efforts and prevention programs. In the UK, the number of suicides in 2018 were the highest since 2002 with an increase of 11.8% the last year, showing a particularly concerning increase of suicide rates among persons under 25 years of age (3).

Compared to other countries, it is reasonable to assume that the implementation of specific prevention programs in Norway may have had some effect. There is, however no indication of a decreasing suicide rate in Norway despite increased resources in mental health care.

High risk populations: For a large proportion of patients admitted to psychiatric hospitals, an increased risk of suicide is the main reason for admission. A recent study showed that 72 % of the patients admitted at the Department of acute psychiatry, St. Olav University Hospital, were referred for an assessment of increased risk of suicide (4). The priority in the initial treatment is to address both the suicidal state and the acute psychiatric condition leading to increased suicidal risk.

The highest suicide rates are during inpatient stay and in the period from the first days to a few weeks after discharge (5). The suicide risk remain elevated during the first 2 years after discharge (4), prolonging to a lifelong increased risk of suicide. A systematic review and meta-analysis (6) shows that ongoing or recent treatment for a psychiatric disorder or substance abuse constitutes the category with the highest predictive property.

Assessment of suicide risk: Traditionally, clinicians have mainly assessed predictors associated with increased risk of suicide, such as presence of a psychiatric disorder, a substance problem, male sex, higher age, or comorbid somatic disorders. Predicting suicide risk in both short and long term based on these criteria is considered very challenging. Commonly used rating scales can predict repetitive self-harm to some degree, but they cannot predict suicides in a satisfactory, meaningful clinical manner (7). The timeframe from decision to carrying out suicide may be as short as ten minutes or less (9), showing the importance of detecting these high-risk patients and starting preventive measures at an early stage.

Recently, research groups have focused on determining the acute mental state preceding a suicide attempt. The development of an acute suicidal diagnosis; the Suicide Crisis

Syndrome (SCS), is aimed at detecting this state to better treat individuals at high risk (8). The SCS has five main evidence-based components: Feeling of entrapment, affective disturbance, loss of cognitive control, hyperarousal, and social withdrawal. The SCS may provide clinicians with the ability to identify individuals who are experiencing an acute pre-suicidal mental state, regardless of their self-reported suicidal ideation.

Treatments and follow-up of high-risk patients:

Several intervention studies have been conducted with the aim to reduce suicide rates. A recent systematic review (10) included both non-pharmacologic and pharmacologic therapies. Treatment with Cognitive Behavioural Therapy (CBT), reduced suicide attempts and suicidal ideation. However, CBT did not prevent or reduce suicide. Medication with lithium in affective disorders reduced the rate of suicide compared to placebo (10). Data on efficacy of the other interventions investigated was limited (10). Some of the studies who focused on developing safety plans for future suicidal crises, documented a reduced number of incidents of suicide attempts and suicides (10). This review also investigated the drop-out rate, showing the important finding that often more than 50% drop out the first week of therapy (10). All trials excluded patients with a history of substance abuse and many of the studies were conducted on selected groups, limiting generalisability.

How can psychoeducation help?

To our knowledge, there are no existing psychoeducational programs aimed at people considered to be at increased risk of suicide. Psychoeducation is widely used as part of the treatment for several psychiatric conditions, e.g. ADHD, personality disorders, bipolar disorders and schizophrenia. For patients with bipolar disorder, group psychoeducation is proven effective to prevent relapse (11). This treatment form provides education and information to both patients and their family members and destigmatize mental health conditions. People who have knowledge of the challenges they face, as well as recognizing personal coping skills, internal and external resources, and their own strengths, are better able to cope with difficulties and feel more in control of their condition. Psychoeducation may provide those at risk of suicide with tools to better understand and communicate experiences of mental pain, hopelessness, and suicidal ideation.

Measuring effect of treatment – level of mental pain and level of self-efficacy:

As suicide is infrequent, even in high-risk population, it is difficult to evaluate whether an intervention is effective. Occurrence of suicide attempts is more frequent (20 attempts to 1 suicide (WHO)), but fewer attempts is not necessarily a measure of lower incidence of suicides.

Higher levels of mental pain have been associated with both suicidal ideations and suicidal acts (13). A systematic review (14) concluded that mental pain is a core clinical factor for understanding suicide in both clinical and non-clinical samples, independent of factors associated with suicidality such as depression, hopelessness and impulsivity. In conclusion, the authors advised that assessments concerning suicidal risk should include evaluation of mental pain (14).

Mental pain has been defined as “a wide range of subjective experiences characterized as a perception of negative changes in the self and its function that is accompanied by strong

negative feelings" (15). Mental pain alone may not lead to suicidal behaviour, but will become critical when the person has no ability to regulate the pain (16)

There has been a growing emphasis on patient-reported outcomes (PROs) where patients report directly how they function or feel in relation to a health condition or the corresponding therapy. Measuring mental pain can therefore be a useful transdiagnostic tool in treatment outcome studies (17).

General self-efficacy is the belief in one's competence to cope with a broad range of stressful or challenging demands and dealing efficiently with unexpected events, handling unforeseen situations, and finding solutions to problems. Studies show that psychoeducation improves self-efficacy (18). Previous studies have shown a correlation between low coping expectations and increased suicide risk (suicidal ideation) and indicated that increased self-efficacy and better coping with emotional situations can have a preventive effect (19, 20).

2.1 Benefits for treatment of patients

General new aspects of the project compared to previous research:

1: To our knowledge, there are no psychoeducational courses for patients assessed with a high suicide risk
2: Most previous studies have been conducted in individual settings. This project is group-based.
3: We are not aware of any study with a design including group-based sessions with the important next of kin.

A recent study prioritized suicide prevention recommendations in specialist mental health care, using the Delphi technique (a technique to achieve convergence of opinion). Five recommendations were prioritized for optimizing the quality of care for suicide preventions: 1) screening for suicidal thoughts and behaviour, 2) safety plan, 3) early follow-up on discharge, 4) continuity of care and 5) involving family or significant others (12). The planned psychoeducative course involves a safety plan, early follow-up on discharge, and involvement of family or significant others.

***Risk assessment*:** Group-based psychoeducation is generally known to be well tolerated and is among the most effective of the evidence-based interventions providing education to enhance the ability to feel more in control of the condition. Psychoeducation for patients with a comorbid severe substance abuse can have a negative effect (21). This patient group will therefore be excluded. For patients with borderline personality disorders, dialectic behaviour therapy is considered more effective. Also, self-harming behaviour without an intention to die is not in the inclusion criteria for this project. Patients with borderline personality disorders will therefore be excluded from the project.

3: Research questions and goals:

Hypothesis: Participating in a group psychoeducative training course will be more effective than one individual session with focus on safety plan to prevent suicide attempts and suicide for patients assessed with a high suicide risk.

Primary outcome:

- The participant's level of self-efficacy after completing the course or session, and 6 months, 12 months, 24 months and 5 years post discharge.

Secondary outcomes:

- The level of mental pain
- Numbers of suicide attempts recorded in the Norwegian Patient Registry (NPR).
- Numbers of suicides recorded from the Norwegian Cause of Death Registry
- Number of admittances and days in psychiatric hospital recorded from NPR.
- Number of compulsory admissions and voluntary admissions recorded from NPR.

An expected result of psychoeducation courses is an increase in voluntary admissions, but fewer compulsory admissions.

We also want to obtain information about prescribed medication use during the project period from the Norwegian Prescription Database (NorPD). When applicable, this will be described in more detail in an updated sub-application to REK.

Topics for articles

This research is a bigger project with possibilities for more publications than this PhD.

Tentative articles for this PhD-project:

1) Evaluation of GSE after 6 and 12 months in the two groups

2) Evaluation of mental pain after 6 and 12 months in the two groups

3) Number of admittances, days in ward and compulsory vs. voluntary admittances in the two groups after 12 months

4. Plan for implementation

4.1 Study design, choice of methods and analyses.

Study design: A randomized controlled trial

Study group: Group based psychoeducative intervention, three sessions for patients and one session for next of kin. One follow-up session within 2-4 weeks.

Control group: One individual session with focus on suicide risk and safety plan with study psychologist or physician.

Both groups: Treatment as usual (TAU) in the outpatient clinic.

Study group: Four weekly sessions, 8-10 participants:

First session: 3 x 45 min: Information on suicidal thoughts, suicide attempts and suicide as a phenomenon with focus on vulnerability factors, risk development and development of the suicidal crisis syndrome.

Second session: 3 x 45 min: Identifying triggers for increase in suicide risk and suicidal impulses, detecting early warning signals for increased suicide risk and how to recognize the change as it happens.

Third session: 3 x 45 min: Completing the individual safety plan (written or using the app "MINPLAN Norge" for android or Iphone) to prevent an increase in suicide risk. The safety plan includes "situations that may trigger increased risk", "how to recognize and communicate the increased risk" and "actions that may reduce or increase risk."

Fourth session: 2 x 45 min: Participants: Aimed at the next of kin that the group participant wants to attend. The topic is a review of the information from the first two sessions, as well as focus on what the next of kin can or cannot do to help if the risk of suicide increases.

Fifth session: Follow-up session within 2-4 weeks for all participants.

Control group: One individual session with focus on suicide risk and safety plan with study psychologist or physician.

Information about the study, inclusion, and randomization

To ensure that the findings are generalizable to patients with high risk of suicide in a psychiatric setting, the following patients will be included with consecutive sampling of patients who meet the selection criteria and give an informed consent:

1: Patients acutely admitted to Department of acute psychiatry, St Olav University Hospital or Levanger Hospital

2: Patients acutely admitted to an outpatient team for acute and emergency psychiatry, St Olav University Hospital

3) Patients admitted to a day ward at district psychiatric centers (DPS)

4: Patients admitted at somatic departments that are evaluated by physicians or psychologists at the Consultation Liaison, St Olav University Hospital.

Criteria for inclusion:

Patients with a suicide attempt, suicidal behavior, or risk of suicidal behavior and a clinician evaluating that the patient has an intention to die.

* Patients with a suicide attempt or suicidal behavior defined as "a self-inflicted, potentially injurious behavior with a non-fatal outcome for which there is evidence of intention of death" (22, 23) and/or considered to have had or been close to a suicidal crisis syndrome (8).

Criteria for exclusion:

1. Not being sufficiently fluent in Norwegian to provide informed consent, valid responses on psychometric testing or to benefit from a psychoeducative course
2. A known diagnosis of ICD-10 F 60.3 with similar symptoms at previous admittances
3. Ongoing psychosis
4. A substance abuse condition to such a degree that they are unable to comply with the protocol and are considered to be at risk when attending psychoeducational courses
5. Organic brain disorders or mental disabilities in such a degree that they are unable to comply with the protocol.
6. Not being able to give an informed consent

When patients are included, the clinicians answer some specific questions about the severity of the condition, to make us better able to describe the patient group included, see attached form (A-SCS).

Study group:

1: Patients acutely admitted to Department of acute psychiatry, St.Olav University hospital or Levanger Hospital

2: Patients acutely admitted to an outpatient team for acute and emergency psychiatry, St Olav University Hospital

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4: Patients admitted at somatic departments that are evaluated by physisians or psychologists at the Consultation Liaison, St Olav University Hospital.

Baseline investigation before inclusion:

- Demographic variables
- AUDIT, DUDIT
- Diagnosis using ICD-10 Criteria for research.

Meeting exclusion criteria

Randomized

Measurements when included:

- A-SCS: diagnostic criteria of SCS (clinician reported)
- SCI-5: symptoms of SCS (patient reported)
- GSE: Level of self-efficacy
- MPQ: Level of mental pain
- PHQ-9: Level of depression
- GAD-7: Level of anxiety

Psychoeducativ training course

Group based psycho-educative intervention: four weekly sessions.

Treatment as usual (TAU) in the outpatient clinic.

Control group:

One individual session with focus on suicide risk and crisis plan with study psychologist or physician.

Treatment as usual (TAU) in the outpatient clinic.

Follow-up:

- At the end of course or session

- 6 months after intervention

- 12 months after intervention

- 24 months after intervention

- 60 months after intervention

Follow-up investigation at the end of finished training course and individual session, and 6-, 12-, 24 months and 5 years after finished course or session.

- MPQ
- GSE-scale
- PHQ-9
- GAD-7
- SCI-5
- AUDIT
- DUDIT
- Numbers of suicide attempts recorded in the Norwegian Patient Registry (NPR).
- Numbers of suicides recorded from the Norwegian Cause of Death Registry
- Number of admittances and days in psychiatric

Sample size:

Participants will be equally randomized (1:1) in the intervention and control group. The primary outcome target is General self-efficacy scale (GSE) scores measured 6 months, 12 months, 24 months and 5 years after the end of intervention.

We want 80% power to demonstrate a clinically relevant difference between intervention and control group in self-efficacy measured by GSE with significance level 0.05. We assume we can use t-test for said comparison as measure of power size.

An increase of ≥ 5 points on the GSE scale is considered the limit for a minimally clinically important change (24). In a large Norwegian population study, the average for the whole group regardless of age, gender and education, was 29 with SD 6.2 (25).

To obtain a power of 80% for a two-sample t-test with mean difference = 5, pooled SD = 6,2, and significance level 0.05, 26 participants are needed in each group, we obtain a power of 80%. To allow for 35% drop-out, we plan to include a total of 80 participants (i.e. 40 in each group).

Randomization and masking of study groups

Participants will be equally randomized (1:1) in the intervention and control group. Patients will be included during admittance in the acute psychiatric ward or when in contact with the outpatient team for acute and emergency psychiatry. The first randomization takes place when sixteen to twenty participants are included. Randomization will take place by manual randomization by an external person at KlinForsk (Klinisk forskningsenhet Midt-Norge). This ensures an equal distribution between the intervention group and the control group. The patient and treating clinician will be unblinded to treatment modality. To compensate for lack of blinding concerning the received treatment, the persons ratings, subsequent measurements and data collection at follow-up will be blinded to the treatment conditions to avoid confirmation bias. The statistical advisor will also be blinded to treatment modality.

Assessments and interventions

Baseline variables includes diagnosis using ICD-10 criteria for research and demographic variables such as age, gender, level of education and occupation.

Following assessments will be used when including patients for the project:

The General self-efficacy scale (GSE) measures optimistic self-beliefs in coping with the demands, tasks and challenges of life in general. It consists of 10 statements that respondents rate on a scale from 1 (not at all true) to 4 (exactly true). The individual's scores on each item are summed up to a GSE score with higher scores indicating higher GSE (24). We added four extra questions to the original form to make sure we had some suicide-specific questions that could capture changes in coping expectations related to symptoms of increased suicide risk.

The mental pain questionnaire (MPQ). The MPQ includes statements on sense of emptiness, loss of meaning and suffering. The statements are formulated on a dichotomous response format. Higher scores indicate higher level of mental pain. MPQ is a simple 10-items self-rating questionnaire and is a transdiagnostic tool. MPQ may qualify as a PRO measure to be included in treatment outcome studies (17).

Alcohol Use Disorders Identification Test (AUDIT): Based on the data from a multinational WHO collaborative study, the AUDIT questionnaire is a simple method of screening for excessive drinking and alcohol use disorders. A score of 8 or more is associated with harmful or hazardous drinking, a score of 13 or more in women, and 15 or more in men, is likely to indicate alcohol dependence.

Drug Use Disorders Identification Test (DUDIT) is an 11-item self-report questionnaire developed to screen individuals for drug problems. A male with 6 points or a female with 2 points or more probably has drug-related problems. Patients with 25 points or more are probably heavily dependent on drugs.

The Patient Health Questionnaire (PHQ-9) is a multipurpose instrument for screening, monitoring and measuring the severity of depression. It is a brief self-report tool consisting of 9 items scored from 0 (not at all) to 3 (nearly every day). Score 0-4 corresponds to no depression, 5-9 mild, 10-14 moderate, 15-19 moderate severe and 20-27 severe depression. Validity has been assessed against an independent structured mental health professional (interview. PHQ-9 score ≥10 had a sensitivity of 88% and a specificity of 88% for major depression (28).

A-SCS (Abbreviated Suicide Crisis checklist): These are the diagnostic critera of suicide crisis syndrome. It is clinician reported with two main items: entrapment and associated disturbances (affective disturbances, loss of cognitive control, disturbance in arousal and social withdrawal). This seems to be an effective tool for detecting short-term suicide risk and to make sure we include the right patients for our project. To cover the SCS-symptoms, we decided to use the abbreviated suicide crisis syndrome checklist (A-SCS) which is more structured than the diagnostic criteria. Two psychiatrists with knowledge on the topic made independent translations. A third psychiatrist combined the translations, and a fourth psychiatrist translated back to English. Author of the form, Dr. Galynker then evaluated and approved the translation.

Suicide Crisis Inventory (SCI): This is a shortened version of the SCI-2. SCI-2 is widely used in American suicide research, but it too comprehensive (60 items) and not compatible with clinical research. The SCI is a 25 items self-report tool that reports the patients self-experienced symptoms of suicide crisis syndrome.

A new and abbreviated version of the SCI, the Suicide Crisis Inventory-5 (SCI-5) is a 5-point scale that covers all five symptoms of the Suicide Crisis Syndrome. The form is tested and validated in a Taiwan study (29) and is compatible with the clinical research in our setting. After a thorough discussion in the research group and with international partners, we concluded that the SCI-5 should replace the SCI in our study. We translated the form from English to Norwegian. Three independent psychiatrists with specialized knowledge on the topic made independent translation. Then a fourth psychiatrist made a combined version that was translated back to English. Author of the form, Dr. Galynker then evaluated and approved the translation. Benefits of using the SCI-5: it is brief, represents all the subscales of the full SCI-2 and has been validated in a recent study (29).

Follow-up questions for the next of kin:

As we include next of kin in this course, we find it interesting to receive information about whether the content is perceived as relevant, whether it contains new and unknown information and whether they believe it will make them better able to recognize early warning signs of increased suicide risk in their loved ones. Therefore, we would like to add a few questions for the relatives at the end of the fourth course. Answering the questions is of course voluntary and will not affect the participation in the course. The answers will be collected digitally by logging in using their BankID. No personal information will be stored, and the answers will be anonymous and not connected to the patients.

Unfortunately, we have not had a user representative available to review the questions in advance. The research group work to recruit new user representatives, and the questions will be presented and evaluated with the user representatives when recruited.

Pre-session

Patients included in the study will be summoned to a pre-session of approximately 15 minutes before they take part in the intervention (either group session or individual session). The pre-session is a phone call, and it will be held a few weeks before the intervention. The purpose of this contact is to make the patients feel safe, give them the opportunity to ask questions and reduce drop out before intervention.

Measures at follow-up:

Following questionnaires will be measured at 6-, 12-, and 24 months and at 5 years after finished course or session: the General self-efficacy scale including specified questions (GSE), the mental pain questionnaire (MPQ), The Patient Health Questionnaire (PHQ-9), the General Anxiety Disorder-7 (GAD-7) and the Suicide Crisis Inventory-5 (SCI-5), AUDIT and DUDIT.

Statistical analysis

The analyses will be performed after last patient out. The main analysis will be performed according to the intention-to-treat (ITT) principle. In ITT analysis all patients are analysed according to their initially assigned study arm at baseline, regardless of adherence to study protocol. Patient who withdrew consent or patients with a protocol violation concerning eligibility are excluded from ITT analysis. We plan to use a linear mixed model with time and the interaction between intervention and time as main covariates, and patient as random effect. Other covariates which are plausibly strong predictors of outcome will be specified in a statistical analysis plan prior to the analysis.

Pilot and feasibility study

We performed a pilot and feasibility study to test the psychoeducational course on patients that filled the inclusion criteria. The intention of the pilot was to figure how many patients wished to participate, how relevant and acceptable the course was, how many of the included patients finished the course and identifying any obvious short term side effects of the course.

Five participants were recruited from the acute psychiatric department with the same inclusion criteria as the main project. The participants completed all three parts of the course and all participants invited a next of kin to a fourth meeting. They filled out the GSE, MPQ and PHQ-9 before inclusion, as well as the CSQ-8 (a scheme to evaluate the satisfaction of the course) at the end of last session.

Briefly summarized findings from the pilot:

- The patient drop-out from inclusion point to course start is considerable and comparable to previous studies (up to 50 % drop-out) (10)

- All over, the participants were satisfied with the course, it met their expectations and were deemed relevant and useful

- The next of kins were thankful for a course where they were included and reported that they were given tools to how they can recognize warning signs and how they can seek help if their relative developed symptoms of increased suicide risk.

- Based on the feedback from the participants we are now able to alter and improve the course before starting the RCT.

Based on our findings from the pilot with a high drop-out rate from inclusion to course start we would like to find out more what happens with these patients. Are they healthy and no longer in need of a suicide preventive course? Are they readmitted? Have anyone committed suicide? We would like to add to the declaration of consent an extra paragraph where the patients can declare for further follow up with diagnostic tools after 6 months, 12 months and 5 years and for us to check their register data even if they do not show up for the course. This is only applicable if the patients has not actively withdrawn their consent.

4.2. Organization and collaboration

Project manager and main supervisor: Katrine Kveli Fjukstad, MD PhD, associate professor at the Department of Mental Health, Faculty of Medicine and Health Sciences, NTNU and psychiatrist at the Department of Psychiatry, Nord-Trøndelag Hospital Trust.

Co-supervisors: Arne Vaaler, Professor, St. Olavs hospital/ NTNU and leader of «Klinisk akademisk forskningsgruppe suicid», Anne Engum, MD PhD, St.Olavs hospital,

PhD candidate: Thine Marita Kirkeby Rishaug, MD

Statistical advisor: Stian Lydersen, Professor of Medical Statistics, Regional Centre for Child and Youth Mental Health and Child Welfare (RKBU), Department of Mental Health, Faculty of Medicine and Health Science

National collaborator: National Centre for Suicide Research and Prevention, Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Fredrik A. Wallby

International collaborator: Mount Sinai School of Medicine, New York, Professor Igor Galynker

The Department of acute psychiatry, St Olav University Hospital has an outpatient team focusing on assessment, treatment and research in patients with bipolar disorder. The team has long experience in conducting group psychoeducation for patients with bipolar disorder. The same group has developed this psychoeducational course an developed a manual aimed at course leaders so that other outpatient clinics can apply the treatment method.

4.4 Progress schedule and publishing plan

	2022		2023		2024		2025		2026		2027		2028		2029		
Pilot and feasibility study	x	x															
Psychoeducational courses and data collection						x	x	x	x	x	X						
Follow-up data and analyses						x	x	x	x	x	x	x	x				
Writing articles										x	x	x	x	x	x		
Submitting thesis																x	
Thesis will be submitted 2029 with data from the first 12 months. Data collection will continue 5 years after after last course is completed, estimated approximately 01.01.2032																	

4.5 Plan for implementation and dissemination

Recruitement of patients will occur according to the descriptions under point 4.1. The results from the project will be published in internationally acknowledged peer-reviewed journals and presented at conferences. Summaries of the results will also be distributed in channels such as research pages for NTNU, Nord Trøndelag Hospital Trust and St. Olav University Hospital. The project will be carried out in collaboration with other hospitals and with the National Centre for Suicide research and Prevention (NSSF, UiO).

6. Ethics

Study protocol is approved by the Regional Committees for Medical and Health research ethics (REK number 142708). The project will be conducted according to international ethical guidelines (The Declaration of Helsinki). Written informed consent will be obtained from all participants included. Participants will receive no payment to participate in the study and will be informed that they can withdraw from the study at any time without stating the reason. Data will be kept unidentified and written material will be locked in a lockable cabinet behind locked door, and electronic data will be stored in a secure area assigned by HEMIT (Central Norway Regional Health Authority's IT department).

Adverse events (AEs)

Even if psychoeducational courses are known to be well tolerated, suicide is a sensitive topic that needs to be handled with care. The course leaders will be available after each session for patients that might need further care due to increased suicidal ideation. All participants from the study group involved in treatment, both for the intervention group and the control group, are responsible for detecting, documenting and follow up of adverse events that are serious or that are considered related to the study intervention or study procedures.

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